that the term "neoplastic disease" in claim 33 fails to find basis in claim 6 as claim 6 uses the term "neoplastic conditions".

Claim 33 has now been amended to change "neoplastic disease" to "neoplastic condition", thus obviating this rejection.

Claims 35-38 have been rejected as being unpatentable over the Sato et al patent of record. The examiner states that Sato teaches compositions employing the claimed 20×10^6 IU of interferon. The examiner states that while the patent does not teach the claimed lozenge or buccal tablet, a showing over the prior form is needed. This rejection is respectfully traversed.

It is respectfully submitted that no showing of unexpected results is necessary if the examiner has not established a *prima facie* case of obviousness. It is urged that the buccal tablet or lozenge form of the composition of the present invention would not have been *prima facie* obvious to one of ordinary skill in the art reading Sato. Sato only teaches liquids and sprays for local application, preferably covering the applied area with a bandage, plaster, tape or the like to prevent removal of interferon from the lesional area. See the paragraph bridging pages 3 and 4 of the specification, as well the following paragraph. There is no suggestion of

applying the interferon in the form of a lozenge or buccal tablet. As Sato desires to topically apply the interferon composition directly to the lesional area, it would not be obvious to take it as a lozenge or buccal tablet. While these dosage forms cause general release within the mouth, they do not cause direct application to a particular lesional area which is what is desired by Sato. Sato teaches that it is desired to prevent removal of interferon by saliva or movement of the tongue.

Accordingly, Sato does not provide motivation to change the topical or local application composition forms disclosed therein to the form of a lozenge or buccal tablet which is not disclosed therein. Accordingly, no *prima facie* case of obviousness has been established. The difference in the dosage forms permitted by the present invention and those disclosed by Sato is due to the difference in intended use of the interferon composition. In the present invention, there is no intent of achieving topical administration but stimulation of the immune system via the oromucosal. Accordingly, the lozenge and buccal tablet dosage form of the present composition claims would not have been obvious to one of ordinary skill in the art reading Sato. reconsideration and withdrawal of this rejection are respectfully urged.

Claims 6, 13, 22-31 and [illegible] have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 and 10-16 of U.S. patent 5,997,858.

Attached hereto is a terminal disclaimer disclaiming the terminal portion of the present application which may extend beyond the term of patent 5,997,858 and agreeing that any patent granted on the above-identified application shall be enforceable only for and during such period that said patent is commonly owned with U.S. patent 5,997,858. With the filing of this terminal disclaimer, this rejection has now been obviated.

It is submitted that all of the claims now present in the case clearly define over the references of record. Reconsideration and allowance are, therefore, earnestly solicited.

Respectfully submitted,

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